

REMARKS

Applicants respectfully request reconsideration of the present application in view of the following remarks. Claims 12-14 and 51-54 remain pending as previously presented.

35 U.S.C. §112, second paragraph

The Examiner has maintained the rejection of claim 12-14, 51-53 and added claim 54 as being indefinite allegedly for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention, “essentially for reasons of record.” Applicant understand this to be an objection to the term “conformer,” which the Examiner alleges renders the claims indefinite. Applicant traverses the rejection.

There is no doubt that one of ordinary skill in the art would understand the meaning of the term “conformer” as it appears in the claims of the present application. To begin, the specification, at page 8, lines 26-28, explicitly defines the term conformer as follows:

The term “conformer” refers to a protein having at least substantially the same amino acid sequence, but heterogeneity in structure (physical topology or topography) and function. By topology is intended the different placement of the protein, e.g. C-cytosolic as compared to N-cytosolic, and topography intends change in external conformation or shape (i.e. different three-dimensional shape due to differences in folding/conformation), which includes stable and transient associations with other proteins.

Further the term conformer, as defined in the specification, is consistent with the common usage of this term in the art. As proof of the common usage, Applicant attaches two articles illustrating the use of the term “conformer.” First, Ribeiro, et al. (attached as Exhibit A), published in 1995, prior to the effective priority date of the present application, discusses a protein that is present *in vivo* in two different conformations, “a native form, which does not bind heparin, and a heparin-binding *conformer*.” (Abstract, emphasis added). The second article, Irnaten, et al. (1998; attached as Exhibit B), demonstrates not only that conformer is a standard term in the art (see abstract and page 954, bottom of second column), but also that use of antibodies is an accepted method of distinguishing between different conformers of the same

protein (abstract and page 955, column 1). Accordingly one of ordinary skill in the art would have no trouble ascertaining the metes and bounds of the claim.

35 U.S.C. §112, first paragraph (written description)

The Examiner maintains the rejection of claims 12-14, and 51-54 under 35 U.S.C. §112, first paragraph, alleging that the specification fails to provide sufficient teaching regarding knockout mice. Applicant respectfully traverses the rejection.

The Office Action states that “the knowledge of knockout mice and the production of such mice is not a trivial matter and that general description would not be sufficient to describe the particular mouse needed for the invention.” Applicant submits that it is well settled that difficult and time consuming is not the same as “undue experimentation.”

Additionally, the Office Action proposes alternative interpretations of Applicants’ data, as disclosed in the specification. Page 5. Applicants do not refute that there may be alternative interpretations of their data. However, what is relevant in the instant prosecution proceedings is Applicants’ interpretation of the data in the specification. U.S. Patent Law does not require that Applicants’ rule out alternative interpretations. Thus, the Examiner’s argument is moot. In addition, Applicant submits that the Examiner has not provided a compelling argument or even addressed Applicants earlier response to this same rejection. Accordingly, Applicants respectfully request the examiner to withdraw the rejection.

35 U.S.C. §112, first paragraph (enablement)

The Examiner also maintains the rejection of claims 12-14, and 51-54 under 35 U.S.C. §112, first paragraph, alleging that subject matter is not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner maintains the rejection based on the alleged unpredictability in the art of making knockout animals. The standard for satisfying the enablement requirement of 35 U.S.C. § 112 is that the disclosure must provide sufficient information to enable one skilled in the art to practice the claimed invention. In re Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991). The claims and specification provide a clear

series of steps that may be followed to prepare the transgenic animals of claim 54 and the monoclonal antibodies of claim 12. The Examiner has not provided any tangible evidence or substantive reasoning to describe why one of ordinary skill in the art would not be able to practice the claim invention without undue experimentation. Applicant respectfully requests the Examiner to withdraw this rejection.

Rejection under 35 U.S.C. § 102(b):

The Examiner rejects claim 13 was rejected under 35 U.S.C. § 102(b) as being anticipated by Willison *et al.* (1989) Cell 57:621-32.

Applicant traverses the rejection. Claim 13 is drawn to monoclonal antibodies (mAbs) produced by the method of claim 12, which in turn depends from the method recited in claim 54. Claim 54 recites a method for making transgenic mice that “produce antibodies that have conformational specificity for a chaperone protein that is involved in assembly of immature HIV capsids and not to conformers of said host chaperone protein that do not bind to Gag and do not facilitate HIV capsid assembly.” This language is not a manipulation of the steps recited in the method claim. Instead, this language recites a characteristic that the claimed antibody must possess.

While Willison *et al.* describe seven mAbs that were able to detect bacterially-expressed TCP-1, this article provides no disclosure of an conformer-specific antibody, *i.e.*, an antibody that has conformational specificity for a chaperone protein that is involved in assembly of mature HIV capsids and not to conformers of said chaperone protein that do not bind to Gag and do not facilitate HIV capsid assembly. While Willison *et al.* disclose antibody 23c, which binds to HP68 isolated from wheat germ extracts, this article provides no disclosure or suggestion that antibody 23c possesses the claimed conformational specificity for a chaperone protein that is involved in assembly of mature HIV capsids and not to conformers of said chaperone protein that do not bind to Gag and do not facilitate HIV capsid assembly. Accordingly, Willison *et al.* does not disclose a monoclonal antibody possessing all of the claimed characteristics and thus cannot anticipate claim 13. Applicant urges the Examiner to withdraw the rejection.

Rejection under 35 U.S.C. §103

The Examiner also rejects claims 13 and 14 as allegedly obvious over Willison et al. Applicant understands the Examiner has maintained this rejection in view of his assertion that the limitation “that have conformational specificity for a chaperone protein that is involved in assembly of immature HIV capsids and not to conformers of said host chaperone protein that do not bind to Gag and do not facilitate HIV capsid assembly” appears in the preamble of claim 54 from which claims 13 and 14 ultimately depend. Applicant is confused by the Examiner’s assertion because this limitation does not appear in a preamble, but rather is a substantive limitation on the antibodies generated by the method of claim 12, from which claims 13 and 14 also depend.

Furthermore, Willison *et al.* cannot be used to support an obvious rejection, at least because (i) the reference explicitly teaches away from antibodies that recognize only one form of a polymorphic polypeptide, such as TCP-1 and provides no motivation to produce conformer-specific MAbs and (ii) the reference does not teach the limitations of “conformational specificity” and “chaperone involvement in HIV capsid assembly as recited in claim 13.

Thus, Applicants submit that obviousness rejection can not be supported by the Willison *et al.* reference, and that the rejection should be withdrawn.

Requirement for deposit

The Examiner rejects claims 13 and 14 under 35 U.S.C. §112, first paragraph, suggesting that a specific antibody is required to practice the claimed invention and requires deposit of antibody 23c. As Applicant has discussed above, one of ordinary skill in the art, using standard techniques available at the time of filing the instant application, would have been able to generate a transgenic mouse according to claim 54 and a monoclonal antibody according to claim 12. Accordingly, deposit of a specific antibody is not necessary to satisfy the requirement of 35 U.S.C. § 112. Applicant respectfully requests the Examiner to withdraw this rejection.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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